DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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To: Kathryn Zoon, Ph.D.
Scientific Director, NIAID

From: Director, Division of Occupational Health and Safety, NIH

Subject: RML Inspection Visit Report and Follow-up visit

This memorandum serves as documentation of an inspection site visit I made to the Rocky Mountain Laboratories, Hamilton Montana during March 21-22, 2006 in compliance with the RML Settlement Agreement. The inspection visit was divided into three general areas: General Safety, Biological Safety, and Facilities. All laboratory facilities and animal areas were visited; policies, programs and standard operating procedures were reviewed for adequacy and record keeping was reviewed. A follow-up visit was made July 25-27, 2006.

The RML safety staff consists of one industrial hygienist (IH), one biological safety officer (BSO), and an environmental technician who splits time between the environmental program and the occupational health and safety program.

General Safety

During the General Safety part of the inspection all written programs and standard operating procedures provided were reviewed. These included procedures and programs such as Hazard Communication, Chemical Hygiene, respiratory protection, confined space entry, and hearing conservation programs, spill and emergency response plans, lock out/tag out procedures, evacuation and ambulance plans, fire alarm procedures, irradiator emergency response, etc. The documentation reviewed was well written, and clear and training was provided for employees affected by these plans and procedures. A Public Access Defibrillator (PAD) program in compliance with the General Services Administration and Department of Health and Human Services guidance for PAD programs was in place. Of special note, and to be commended, the defibrillator units across campus are checked daily to determine that they are functioning appropriately. During the inspection, all laboratory buildings were visited. Hallways were clear and laboratories were generally uncluttered. Laboratory doors opening into general access corridors were closed. A break area was provided for consumption of food and drink by RML employees. Proper signage was used to notify personnel of particular hazards that may be present within a given laboratory or area. Required initial and annual refresher training in laboratory safety, hazard communication and bloodborne pathogens is provided and appropriate training records are kept. Laboratory safety surveys are conducted annually and beginning last year are coordinated with the biological safety surveys performed by the RML biological safety officer. Training sessions required for fork-lift operators and other for other industrial operations are conducted annually by the IH. All laboratory inspection reports for the past three years were reviewed. Appropriate records are kept, results are provided to the designated laboratory personnel, and corrective action plans are requested and followed-up. Eye washes are tested weekly in the animal facilities by animal care personnel and eye washes and safety showers are

tested monthly by the RML environmental technician in other areas of the facility. Fire doors and extinguishers are inspected once per month.

General Safety Recommendations

- The hearing conservation program should be expanded to include noise surveys of potentially problematic areas (mechanical rooms, electron microscopy rooms, etc.)
- A formal ergonomics program would benefit RML employees.
- Resources should be allotted to provide appropriate industrial hygiene monitoring equipment at the lab such as sampling pumps, octave band analyzer, direct reading formaldehyde instrument, Portacount for quantitative respirator fit testing, etc. This equipment now has to be rented if needed.

Biological Safety

The RML has a properly constituted, active Institutional Biosafety Committee (IBC) with a broad charter that includes the typical review of recombinant DNA registration documents in compliance with the NIH Guidelines for Research with Recombinant DNA Molecules and NIH Manual Chapter 3035, Working Safely with Hazardous Biological Materials. Additionally, the IBC provides advice to the RML Biological Safety Officer and Industrial Hygienist; reviews human pathogen registration documents; reviews recommendations made by the BSO; reviews summary reports and audits; receives Responsible Official Reports (Select Agents); and establishes working groups as needed to address any special situations or concerns. In addition to the IBC, RML has established a Biological Exposure Action Team (BEAT) to provide rapid, appropriate response in the event of a potential employee exposure to an infectious agent. Occupational Medical Services are provided through Marcus Daley Home Care by a physician specializing in internal medicine and a nurse. Of special note, Marcus Daley has expanded its capability to provide occupational medical support by hiring both an occupational health coordinator and a certified occupational health nurse. The RML also has obtained the services of an infectious diseases specialist in the event that there is need for this expertise in response to a laboratory-acquired infection and to begin preparing standard operating procedures for work with exotic agents in the RML Integrated Research Facility scheduled to open in 2007. The RML collects and stores baseline sera, as appropriate, for laboratory and at-risk personnel. There is a dedicated serum storage freezer, inventory system, and emergency back-up power for the storage freezer. The inventory is managed by the RML BSO. The RML has 15 certified shippers trained in the packaging and shipment of potentially hazardous (including infectious) materials. During in-depth review of the biological safety program the following documentation was reviewed:

- minutes of the IBC for the past three years
- all human pathogen registration documents (HPRDs)
- all recombinant DNA registration documents
- contract documents for occupational medical services
- SOPs for the Biosafety Level 3 (BSL-3) laboratories
- Standard facility SOPs for Building 25 including two addenda: a) RML Emergency Response Plan; b) Bldg. 25 Security Plan
- Medical incinerator operational parameters and data

IBC meetings are held routinely, on the RML campus, as dictated by work load. The BSO is establishing an electronic review process. Protocols are passed by 2/3 vote of the committee. Review of the minutes revealed that the IBC had suggested a BSL-3 accident drill/simulation. This was discussed at the IBC meetings of November 17, 2003, February 24, 2004 and May 18, 2004. At the time of the site visit, this activity had not taken place though the RML has

participated in a number of table-top emergency response exercises. The BSO reviews and approves human pathogen registration documents, assigns biosafety levels and reports to the IBC; however no record of the biosafety levels assigned or any subsequent discussions are reported in the IBC minutes. During review of the HPRD and recombinant DNA registration documents it was noted that some of the work begun prior to 2004 had not been updated. Since the March site visit, the current BSO has established an electronic database for tracking HPRDs and has begun working with Principal Investigators to insure that biosafety documentation (HPRD and recombinant DNA registration) is current and reflects the work being performed. In only one instance did I disagree with the biosafety level established for working with a particular agent. Upon speaking with the PI, I found that the organism was not being used at RML; the PI did not anticipate use of the organism in the future and agreed to destroy the organism. The destruction was documented by the PI in an e-mail to the BSO.

Notably, and to be commended, the BSO and the RML Animal Program Director have each established training labs for personnel who will be wearing positive pressure, supplied air suits within the IRF. Annual biosafety and general safety training is conducted by the BSO and IH. SOPs specific for infectious agents being used in all BSL-3 laboratories contain safety information, signs and symptoms of disease, required personal protective equipment, waste handling and disinfection/decontamination procedures, etc. At the time of the site visit, protocols for response to nonhuman primate bites and scratches could not be produced by the BSO but were subsequently provided by the animal facility. RML has agreed to update these protocols to reflect the NIH policy and procedures for nonhuman primate-caused injuries.

Certification of all facility HEPA filter installations, biological safety cabinets, and other HEPA-filter containing equipment is provided the Division of Occupational Health and Safety, NIH, once per year and additionally on an "as requested" basis. This situation is not ideal at this time and the RML's need for this service will expand with the opening of the IRF and renovation or replacement of other research facilities.

Biological Safety Recommendations

- All HPRDs and recombinant DNA registration documents, older than 2 years, should be updated and resubmitted by the PI to the IBC to ensure that the records adequately reflect the current nature of the research being performed. These records must be updated annually or more frequently when the science changes, animal studies are added, or when personnel are added or deleted from the protocol.
- The IBC should formally delegate review of HPRDs to the BSO; this delegation should be recorded in the IBC meeting minutes.
- IBC meetings must provide a forum for scientific and risk assessment discussion. Electronic review may not adequately allow for this exchange and the 2/3 vote may not adequately address concerns raised by a minority of members. A consensus process is recommended.
- A BSL-3 accident scenario/simulation should be conducted as requested by the IBC in 2003 and again in 2004.
- Serum samples should be stored in multiple aliquots to prevent damage caused by multiple freeze-thaw cycles should they be needed as a baseline sample subsequent to a potential exposure.
- Bite scratch kits consistent with NIH policy should be provided in nonhuman primate facilities and personnel trained regarding the location and proper use of these kits.

- As the biocontainment capacity of the RML continues to increase, two RML-based HEPA technicians will be necessary to service the site.
- Ducted biological safety cabinets in BSL-3 laboratory areas, must be left on at all times to ensure that directional airflow into the laboratory is not compromised.

Facilities

The facilities are generally well kept and physical hazards are addressed quickly when identified by the IH. There are no PCB-containing transformers or light ballasts. There are still one or two buildings remaining on the campus for which lead paint is a concern. These have been identified by the IH and any lead-containing paint will be addressed as renovations at the campus continue. Areas containing asbestos are limited but have been identified by the IH and facility maintenance personnel. Repairs to friable asbestos are made as these areas are identified and asbestos is removed as part of the renovation process at RML. A facility biocontainment unit has been established, separate from the maintenance and repair unit, to provide specialized support to RML BSL-3 and 4 facilities. The BSO and the Facility Containment Specialist have good communication and work well together. They have developed a new call procedure for rapidly addressing any biocontainment facility concerns.

There was one outstanding facility issue at the RML. Building 13B, a BSL-2 facility, currently has a main corridor used as an extension of the laboratory. Laboratory doors are propped open at all times to allow personnel more efficient and safer access to equipment used in the corridor. The door to the building has been posted at BSL-2, effectively making the corridor an extension of the laboratory. This, however, is not an optimal solution to the problem. Biosafety cabinets throughout have been placed adjacent to doors from the labs that open to the outdoors. There are large exhaust grilles over laboratory doors, in the corridor, that ensure that laboratory contaminants enter the hallway. This laboratory building should be renovated to provide space better suited to the conduct of modern biomedical research.

There are approximately six motor vehicle accidents per year at the RML. These accidents have occurred, in large part to employees parking vehicles within the fenced grounds of the RML. The parking areas have become tighter since the campus fence was installed and the visitor center constructed, resulting in an increased number of “fender benders”.

Facility Recommendations

- Consider renovation/replacement of Building 13B
- Consider ways to relieve the cramped parking situation within the fenced RML grounds.

In general, the RML safety program is well-run and effective. Safety staff were receptive to recommendations for improvement. As the research portfolio at the RML continues to increase, however, the current safety staffing level and resources will no longer be adequate. If I can be of assistance in planning for the anticipated expansion, please fell free to contact me.

Deborah E. Wilson, DrPH, CBSP

Responses to recommendations in DOHS bi-ennial safety inspection of RML December 12, 2006

Provision 15 of the Settlement Agreement reached by the parties in the *Coalition for a Safe Lab v. National Institutes of Health* (NIH) lawsuit and the Order issued by Judge Molloy implementing the Settlement Agreement stipulated that the NIH's Division of Occupational Health and Safety (DOHS) perform a safety inspection at Rocky Mountain Laboratories (RML) every 2 years and make the results of that inspection available to the public. In compliance with that provision, Dr. Deborah Wilson, Director of DOHS, NIH, inspected RML during the spring and summer of 2006 and submitted a report to Dr. Kathryn Zoon, Director, Division of Intramural Research, National Institute of Allergy and Infectious Diseases (NIAID), NIH. Dr. Wilson's report to Dr. Zoon is dated August 30, 2006.

The inspection report addressed General Safety, Biological Safety, and Facilities. The results of the inspection were extremely positive, but there were several specific recommendations made in each area.

This document provides in a narrative form the responses to the various specific recommendations made in Dr. Wilson's inspection report.

- General Safety Recommendations
  - The hearing conservation program should be expanded to include noise surveys of potentially problematic areas (mechanical rooms, electron microscopy rooms, etc.)
    - Response: The current RML Hearing Conservation Program will be updated/expanded and will include all areas with the potential for noise levels near and/or above the OSHA 85 dBa action level. This includes but is not limited to the mechanical rooms, incinerator building, boiler building, etc. Additional noise monitoring equipment including dosimeters were provided to RML by NIH DOHS to facilitate this program expansion.
  - A formal ergonomics program would benefit RML employees.
    - Response: A formal campus-wide ergonomics program will be developed and implemented at RML. This will be incorporated into the current program which provides ad hoc ergonomic assessments and ergonomic training sessions at RML. The program will focus on reduction and prevention of musculo-skeletal injuries.
  - Resources should be allotted to provide appropriate industrial hygiene monitoring equipment at the lab such as sampling pumps, octave band analyzer, direct reading formaldehyde instrument, Portacount for quantitative respirator fit testing, etc. This equipment now has to be rented if needed.

- Response: NIH DOHS allocated the necessary resources during fall 2006, and has provided RML with the listed industrial hygiene equipment.

- Biological Safety Recommendations
  - All HPRDs (Human Pathogen Registration Documents) and recombinant DNA documents, older than 2 years, should be updated and resubmitted by the PI to the IBC (Institutional Biosafety Committee) to ensure that the records adequately reflect the current nature of the research being performed. These records must be updated annually or more frequently when the science changes, animal studies are added, or when personnel are added or deleted from the protocol.
    - Response: Currently there are no HPRD documents older than 2 years. The process of reviewing all Recombinant DNA documents older than 2 years has been started by the BSO (Biological Safety Officer). The first set of documents will be reviewed by the IBC at their next quarterly meeting, scheduled for December, 2006.
  - The IBC should formally delegate review of HPRDs to the BSO; this delegation should be recorded in the IBC meeting minutes.
    - Response: At its quarterly meeting on 9-28-06, the RML IBC gave written delegation to the BSO to review and approve minor modifications and updates to HPRDs, registration documents for Recombinant DNA Experiments, and Standard Operating Procedures (SOPs) for BSL-3 projects. The approved documentation was incorporated into the RML IBC charter.
  - IBC meetings must provide a forum for scientific and risk assessment discussion. Electronic review may not adequately allow for this exchange and the 2/3 vote may not adequately address concerns by a minority of members. A consensus process is recommended.
    - Response: The RML IBC discussed electronic review at both the 6-8-06 and 9-28-06 meetings. The committee decided to continue electronic review. The committee discussed the importance of consensus in decision making, and decided to adopt procedures that the committee felt would allow for adequate discussion and dissent. These procedures were approved at the 9-28-06 meeting and added to the RML IBC charter.
  - A BSL-3 (Biosafety Level -3) accident scenario/simulation should be conducted as requested by the IBC in 2003 and again in 2004.
    - Response: In November 2005, RML held an advanced table-top exercise on the RML campus that involved 49 participants including RML personnel, local emergency responders, and public health officials. The scenario for this exercise involved a mobile crane at the IRF (Integrated Research Facility) construction site toppling onto the building housing the BSL-3

laboratories. RML is committed to additional training, with a functional exercise planned for 2007.

- Serum samples should be stored in multiple aliquots to prevent damage caused by multiple freeze-thaw cycles should they be needed as a baseline sample subsequent to a potential exposure.
  - Response: As of August, 2006 all employee serum samples are received in 2 aliquots and stored separately in 2 freezers.
- Bite Scratch kits consistent with NIH policy should be provided in nonhuman primate facilities and personnel trained regarding the location and proper use of these kits.
  - Response: Bite Scratch kits consistent with NIH policy will be provided in nonhuman primate facilities and personnel trained regarding the location and proper use of these kits.
- As the biocontainment capacity of the RML continues to increase, two RML-based HEPA (High Efficiency Particulate Air) technicians will be necessary to service the site.
  - Response: Two full-time HEPA technicians on site at RML will be provided through the ENV Service contract to service the HEPA filters. This will supplant the current situation where the contracted HEPA technicians service RML on a periodic schedule. The first technician is scheduled to arrive late December 2006/early January 2007. The second technician is scheduled to arrive in early spring 2007.
- Ducted biological safety cabinets in BSL-3 areas, must be left on at all times to ensure that directional airflow into the laboratory is not compromised.
  - Response: Laboratory personnel working in the BSL-3 have been notified of this new requirement to keep the biosafety cabinets on. This requirement has also been incorporated into both the new employee safety training and the annual refresher safety training given to all employees.

- Facility Recommendations
  - Consider renovation/replacement of Building 13B.
    - Response: Planning for renovation to address the described concerns in Building 13B has already begun. Funding has been secured and the process is presently in design phase.
  - Consider ways to relieve the cramped parking situation within the fenced RML grounds.
    - Response: This issue will be addressed during the Master Plan process.